

44

(12) UK Patent Application (19) GB (11) 2 104 360 A

(21) Application No 8219114

(22) Date of filing
2 Jul 1982

(30) Priority data

(31) 280999

(32) 6 Jul 1981

(33) United States of America
(US)

(43) Application published
2 Mar 1983

(51) INT CL³ A61N 5/06
H05B 3/00

(52) Domestic classification
H5H 111 112 126 130
140 152 170 176 177
198 211 231 234 260
274 AAX
A5R EH
U1S 1067 1980 A5R
H5H

(56) Documents cited

GB 1119925

GB 1076449

GB 0812871

EP A1 0021415

(58) Field of search

A5R

H5H

(71) Applicant

Jerry Duane Maahs
19230 Glen Kerry Drive
Brookfield
Wisconsin 53005
United States of
America

(72) Inventor

Jerry Duane Maahs

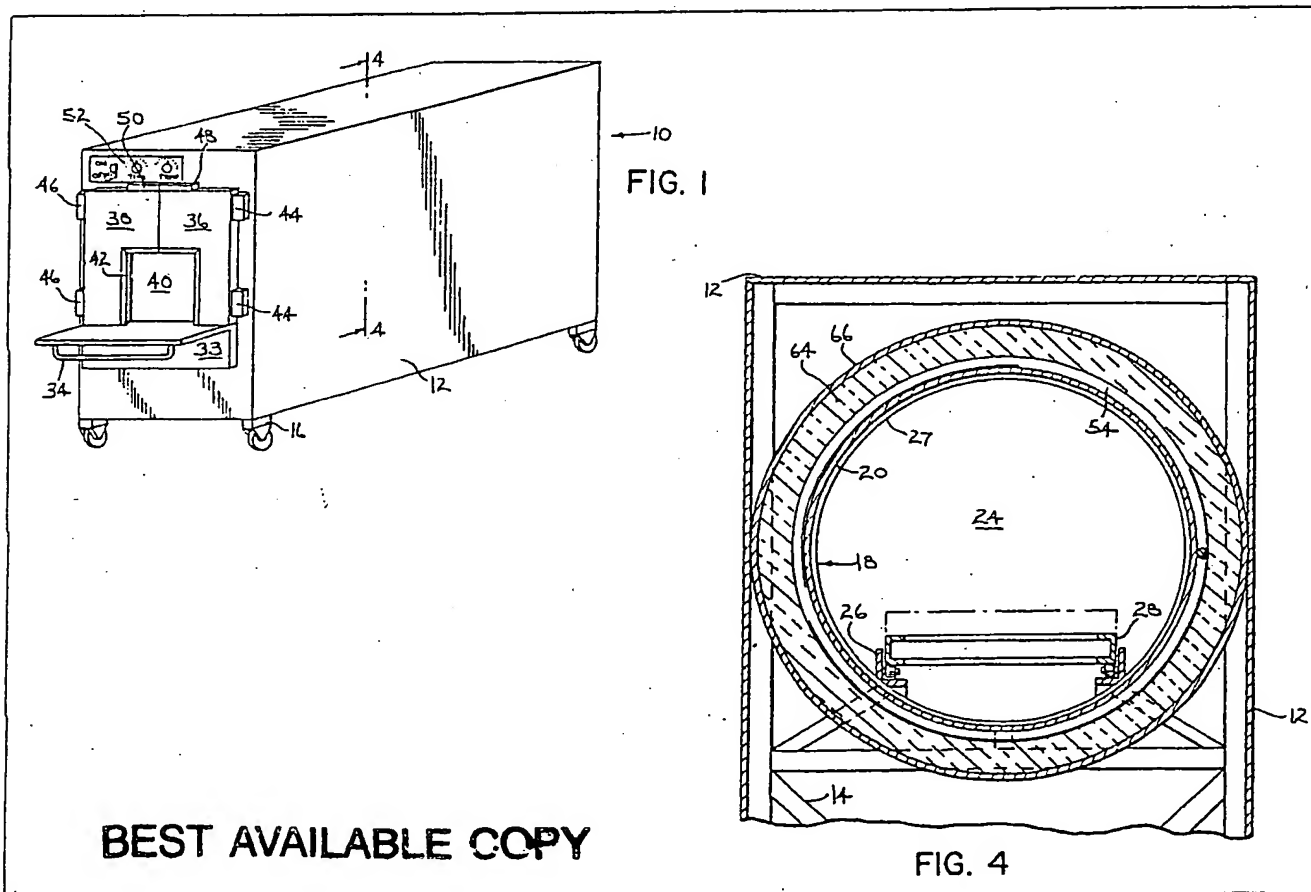
(74) Agents

Gill Jennings and Every
53-64 Chancery Lane
London WC2A 1HN

cavity for receiving the subject. An electric heating cable (54) is placed on the exterior of the wall means for heating the wall means and radiating heat to the subject. A circuit is connectable to a source of electric power for energizing and controlling the heating cable.

(54) Mammalian subject heating unit using radiant heat

(57) A heating unit (10) using radiant heat provides core temperature increases in mammalian subjects, including humans, for cancer treatment or other purposes. The unit has a wall member (18) defining a



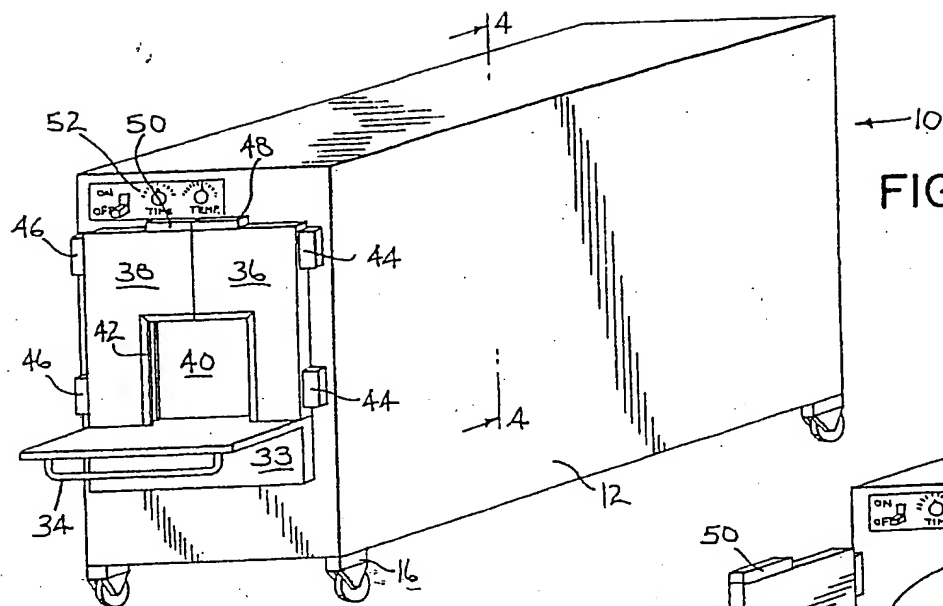


FIG. 1

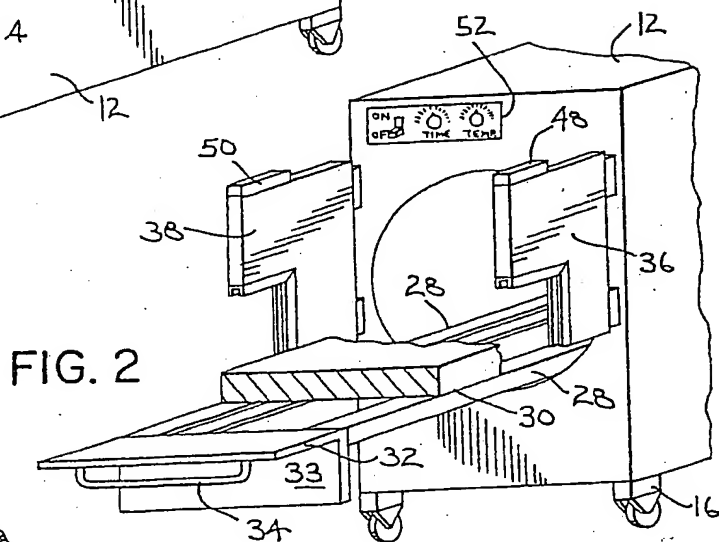


FIG. 2

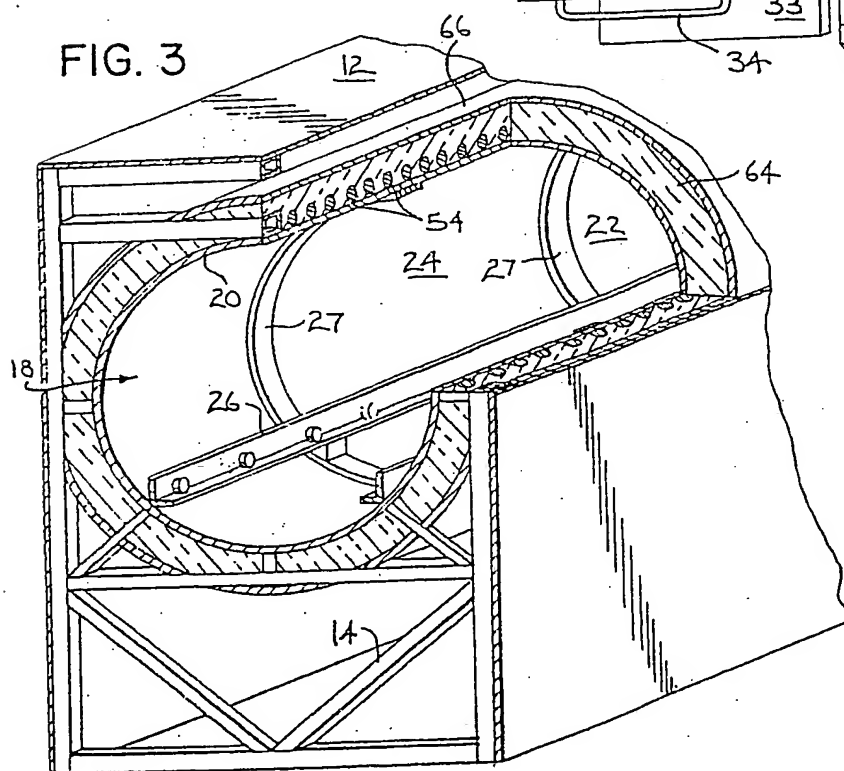


FIG. 3

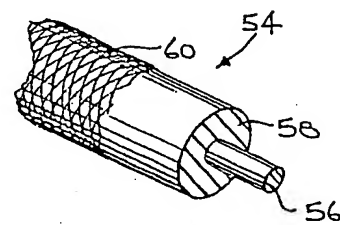


FIG. 5

2/2

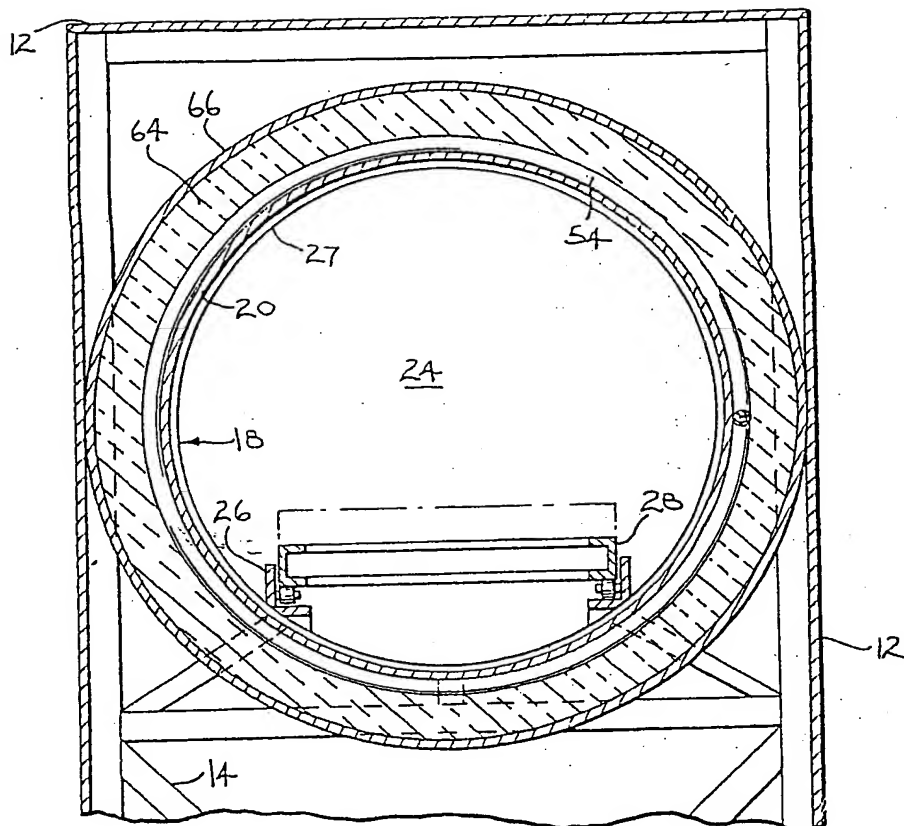


FIG. 4

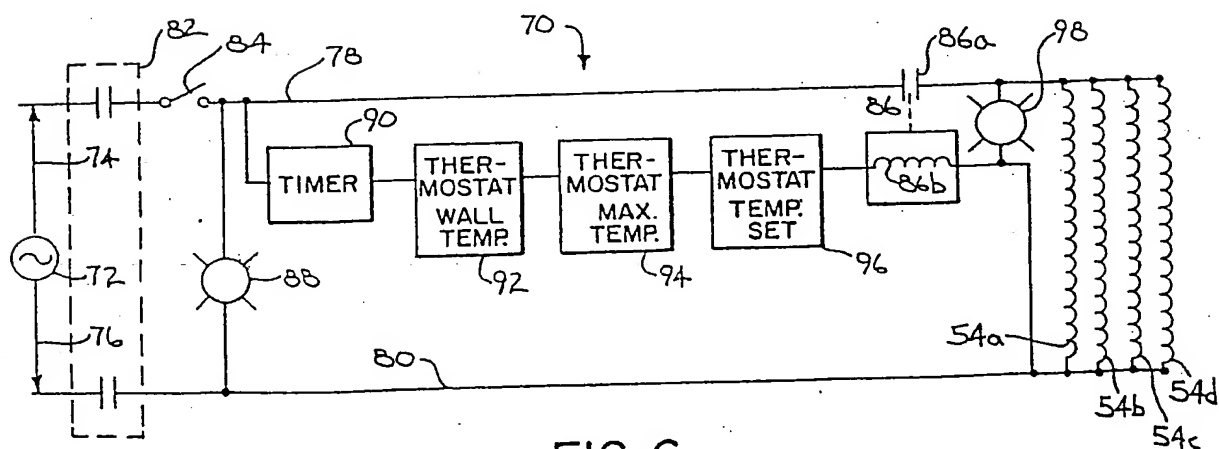


FIG. 6

SPECIFICATION

Mammalian subject heating unit using radiant heat

5 The present invention relates to a heating unit for live mammalian subjects, including humans. The unit employs radiant heat to increase internal temperatures, including increases to elevated levels considered to have a therapeutic effect on cancer.

10 Cancer is currently treated by surgery, radiation, chemotherapy, immunotherapy, or combinations of the foregoing. However, there is increasing recognition that hyperthermia—a condition of greatly elevated body temperature—may provide significant therapeutic effects on cancer, including that not responsive or amenable to conventional treatment. Hyperthermic treatment of cancer involves raising the temperature of the patient to 41.8–42°C (approximately 107°F) and maintaining that temperature for a predetermined period of time. The entire body of the patient is usually heated so that the technique has become known as “whole body hyperthermia”. Hyperthermia is typically used in combination with other treatment such as chemotherapy or radiation.

20 To date, a variety of techniques have been used to produce the hyperthermic condition. These techniques include immersing the patient in hot wax; placing the patient in a suit or under a blanket containing ducts for heated fluid; withdrawing blood from the body, heating it, and returning it to the body; diathermy in which an R-F coupling is established between the body and a high frequency energy source; and applying ultrasonic energy to the patient. However, such approaches exhibit one or more limitations or shortcomings. These include the need for general anesthesia with the attendant medical risk, the need for specialized personnel and/or facilities, the danger of burns to the patient due to heat concentration or hot spots in the equipment, the possibility of blood damage to the patient, extensive and complex temperature monitoring and regulation apparatus, prolonged heating times, and cumbersomeness of the equipment.

50 Further, inasmuch as hyperthermia is carried out at temperatures only slightly below those that can cause death, the operating characteristics of the apparatus used to establish and maintain the hyperthermic condition can be extremely critical.

60 It is, therefore, the object of the present invention to provide apparatus for raising the core temperature of live mammalian subjects, including humans, to a desired level with a commensurate degree of safety.

65 In accordance with the present invention, such apparatus comprises a wall member defining a confined space suitable for receiving

at least a selected portion of the subject, said wall member being formed of a material capable of radiating heat;

70 means for positioning the subject portion in the space defined by said wall member;

electric heating means mounted on the exterior of said wall member generating a heat input to the wall member for providing sufficient radiant heat from the wall member to the subject portion to increase the core temperature of the subject by a physiologically significant amount in a desired period of time, said wall member and heating means providing such radiant heat at a density low enough to minimize the possibility of superficial tissue damage to the subject; and

80 circuitry means connectable to a source of electric power for energizing said electric heating means.

85 The wall member is typically a cylindrical copper sheet closed at one end and containing sealing doors at the other. The electric heating means may be a cable applied in a uniform pattern over the cylindrical sheet and covered with insulation. The cable is preferably a plurality of segments energized in parallel to provide low density, uniform radiant heat sufficient to raise the core temperature to the desired level during an appropriate time period while avoiding burns or other skin injury, as from localized hot spots.

95 The apparatus provides close control of temperature and a high degree of repeatability. Temperature sensors are included in the circuitry for controlling the energization of the electric heating cable responsive to wall member temperature and to desired and maximum permissible temperatures in the chamber.

100 The present invention is low in cost with respect to both apparatus costs and treatment costs. It is anticipated that the present invention will permit elimination of general anesthesia to the patient. This will reduce the attendant requirements for highly specialized personnel and facilities and permit carrying out hyperthermic treatment with a smaller number of people trained in hyperthermia.

110 While the present invention is described herein in the context of hyperthermic treatment of cancer it will be appreciated that other applications may well arise. For example, the apparatus may be used to treat victims of exposure by safely restoring their depressed body temperatures to the normal level. The possibility of its use in the treatment of diseases of the joints also comes to mind.

In the drawings:

125 *Figure 1* is a perspective view of the radiant heat body heating unit of the present invention.

Figure 2 is a fragmentary perspective view of the unit showing additional details thereof.

130 *Figure 3* is a partially cut-away perspective view of the unit.

Figure 4 is a cross-sectional view taken along the line 4-4 of Fig. 1.

Figure 5 is a cut-away view of an electric heating coil suitable for use in the present invention.

Figure 6 is a schematic diagram showing circuitry for energizing the electric heating cable.

Fig. 1 shows apparatus 10 of the present invention for raising the internal or core temperature of live animals, particularly mammalian subjects, including humans. Apparatus 10 includes housing 12 mounted on framework 14, shown most clearly in Figs. 3 and 4. Framework 14 includes coasters 16 lending mobility to the unit.

Wall member 18 is supported by framework 14. As shown most clearly in Fig. 3, wall member 18 includes wall 20 sealed by disc 22 at one end to form a tubular chamber 24, in which the subject or a selected portion of the subject, such as his/her body is received, as hereinafter described. The cylindrical configuration of wall 20 assists in even heat distribution in chamber 24. Wall member 18 is preferably formed from sheet copper material so that the member has an emissivity that enhances its effectiveness as a radiator. Copper is a good uniform conductor of heat helping to avoid localized hot spots and skin burns to the subject. Copper also has good heat retention properties providing consistent temperatures by avoiding sudden temperature changes.

Rails 26 are positioned on wall member 18 for receiving carriage 28 for stretcher 30 on which the subject is placed. Rails 26 may be mounted on bands 27 that extend around the interior of wall 20 in the middle and rear of chamber 24, as shown in Fig. 3. Bands 27 may be expanded by toggle mechanisms, not shown to clamp the bands, and hence rails 26, to wall 20. The use of bands 27 avoids the need to puncture wall 20 and the need for seals and the like to maintain the integrity of chamber 24. The cleaning of chamber 24 is also facilitated since bands 27 and rails 26 can be removed from chamber 24.

Carriage 28 includes head rest 32 for the subject, a panel 33 that assists in closing chamber 24, and a handle 34 by which the carriage, stretcher, and subject are moved into and out of the chamber 24.

The open end of the wall member 18 is closed by a pair of insulated doors 36 and 38 forming opening 40 through which the neck of the patient extends so that his/her head can rest on head rest 32. Doors 36 and 38 are shaped as an inverted L and have retaining means such as channel 42 for receiving a sealing collar that goes around the neck of the patient to seal opening 40. The doors are sealed at the bottom by head rest 32. Doors 36 and 38 are provided with hinges 44 and 46 along outer edges and held closed by

magnetic latches 48 and 50 at their inner edges. Doors 36 and 38 and head rest panel 33 may be provided with gaskets that seal these elements to wall member 18 or housing 12 when they are closed. Because the head rest 32 is coupled to stretcher 30 and because L-shaped doors open in the center, the insertion and, particularly, removal of the subject and associated medical equipment and instrumentation from chamber 24 is facilitated. In emergencies with humans, the patient can be removed from chamber 24 by pulling handle 34 outwardly and allowing the patient's shoulders to swing open doors 36 and 38.

Housing 12 includes control panel 52 for the electrical circuitry shown in Fig. 6.

Means are provided on wall member 18 to heat the wall member and chamber 24. As shown in the Figures, such means may comprise electric heating cable 54 wrapped about the exterior of wall 20 so that the wall member can assist in diffusing the heat from the cable. The cable may be wrapped circumferentially, as shown in Fig. 3 and the turns spaced along the periphery of the wall member to provide uniform heating to the wall member to avoid establishing localized hot spots on wall member 18. The turns of cable 54 will typically be uniformly spaced along wall 20, possibly with minor variations because of frame 14 or other localized anomalies. A retaining or spacer means, not shown, may be provided to hold cable 54 in position on wall 20. Cable 54 is available from several sources including the Continental Wire and Cable division of Anaconda Copper Co. and the Wire and Cable Division of the General Electric Company. As shown in Fig. 5, cable 54 may comprise an internal metal resistance wire 56; an asbestos, plastics or rubber sheath 58 surrounding and insulating the wire; and an outer braided metal jacket 60 for armoring and electrically grounding the cable. Electric resistance wire 56 may be a single conductor of 19 or 20 gauge having a resistance of approximately 675 ohms per circular mil foot at 20°C. The conductor is surrounded by 0.114 cm (.045 inch) thick silicon rubber sheath 58 and a nickel plated copper shield braid.

The heating of wall member 18 by the heating means, such as cable 54, is subject to two, somewhat divergent, considerations. A sufficient quantity of radiant heat must be provided from wall member 18 to raise the core temperature of the subject in chamber 24 by a physiologically significant amount in a desired period of time. The physiologically significant temperature increase may be that necessary to cause the subject to enter the hyperthermic state. In accordance with this consideration, cable 54 may provide a heat input sufficient to raise the core temperature of the subject at least 4° within a period of

120 minutes by the radiant heat in the chamber 24. More particularly the apparatus should be capable of raising the core temperature of the subject 4° to 5°C in a period of 60 to 120 minutes.

At the same time, however, the density of heating, or heat output per unit area of wall member 18, should be sufficiently uniform and low as to minimize the possibility of superficial injury to the subject, such as burns, from wall temperature conditions, and particularly from localized hot spots in the wall member.

The weight of the subject may serve as a factor in the selection of the heat input from the electric heating means. For heating animal subjects having a weight of 70 kg (154 lbs) in an appropriately sized chamber 24, an electric heating cable having a power rating of about 1,000 watts has been employed.

As shown most clearly in Fig. 4, tubular wall member 18 and cable 54 are surrounded by an insulating material 64 such as glass fiber insulation, that is held on tubular member 18 by wrapper 66 formed of metal or other material.

Electrical circuitry for energizing heating cable 54 is shown in Fig. 6. Heating cable 54 is preferably divided into a plurality of segments connected in parallel to ensure even heating throughout tubular chamber 24. This may be accomplished by the appropriate electrical connection of taps along the heating cable. Fig. 6 shows, for exemplary purposes, heating cable 54 divided into four quarter segments 54a, 54b, 54c and 54d.

Circuitry 70 is connectable to an a.c. power source 72, such as conventional 120 volt, 60 cycle alternating current supply 72 having energized line 74 and neutral line 76. Conductors 78 and 80 of circuitry 70 are connected to lines 74 and 76 and contain ground fault interrupter 82 requiring manual reset. Ground fault interrupter 82 deenergizes circuitry 70 in the event of an electrical failure to lessen or avoid shock hazards in apparatus 10. Conductor 78 contains power switch 84 and relay contacts 86a, which when closed permit parallel energization of heating cable segments 54a through 54d through conductor 80.

Indicator lamp 88 is connected across lines 78 and 80 to indicate when main power switch 84 is closed.

A plurality of elements are also connected across lines 78 and 80 to control the operation of electric heating cable 54. These include timer 90 by which the time period for energizing cable 54 may be established. Thermostat 92, which may be of the normally closed, bimetallic type is placed on wall 20 of wall member 18 to sense the temperature of the wall for deenergizing electric cable 54 in the event the temperature rises above a desired maximum value. Typically thermostat 92

will be set to open at 60°C (140°F) and reclose at 54°C (130°F) and is preferably not operator accessible or adjustable. Limiting the wall temperature to this magnitude lessens or avoids the danger of skin burns from apparatus 10. Thermostat 94 may be mounted in tubular chamber 24 at a location appropriate to sense the temperature inside the chamber. Thermostat 94 may be of the normally closed, fluid expansion type. It is not operator adjustable but is preset to open at the maximum temperature desired in the chamber. This is typically 70°C (160°F). The thermostat will close at 68°C (155°F) and below. Thermostat 96 is also placed in tubular chamber 24 at a location to sense the temperature in the chamber. Thermostat 96 may also be of the normally closed, fluid expansion type and is adjustable by the operator to establish a selected temperature in the chamber less than the maximum temperature established by thermostat 94. The coil 86b of relay 86 is connected in series with timer 90 and thermostats 92, 94, and 96 across lines 78 and 80. Coil 86b operates contacts 86a in line 78. Indicator lamp 98 indicates when relay contacts are closed and heating cable 54 is energized.

In use, the patient may be prepared for hyperthermic treatment in apparatus 10 by light sedation. The temperature indicators necessary to monitor internal temperature will be placed in the patient, as for example, through the use of rectal, esophageal, and/or cardiac probes. Sensors for other physiological functions, such as respiration and heart beat rate, are also applied to the patient.

The patient will be placed on stretcher 30 with his/her head resting on headrest 32. The patient is slid into tubular chamber 24 on stretcher 30 with his/her head outside chamber 24. Doors 36 and 38 are closed and a collar placed around the neck of the patient to tightly seal opening 40 making chamber 24 a closed system. Timer 90 is set for the maximum treatment time. Thermostat 96 is set for the maximum temperature desired in chamber 24. Power switch 84 is closed to energize heating cable 54. The contacts of timer 90, and thermostats 92, 94, and 96 are closed, energizing relay coil 86b of relay 86 and closing relay contacts 86a. This permits energization of electric cable 54. The energization of cable 54 heats copper wall member 18 radiating heat to the patient on the stretcher. The internal or core temperature of the patient is monitored through the temperature probes. The temperatures obtained from the rectal temperature probe are typically considered the core temperature of the patient for treatment purposes. The sealing of opening 40 by the collar causes the perspiration of the patient to maintain a condition of saturation or near saturation in chamber 24 limiting patient heat loss by evaporation. Fluids lost through per-

spiration are restored intravenously. As the temperature of the patient increases, his/her metabolic heat generation increases substantially to supplement the radiant heat from wall member 18 in attaining the hyperthermic state.

When the desired core temperature is reached in the patient, the patient may be removed from tubular chamber 24 and covered with a blanket to minimize evaporative heat losses. Through the loss of thermoregulatory capability brought about by the hyperthermic condition, the desired internal temperature of the patient is maintained by the heat generated by increased metabolic activity without the need for external heat application. When the patient has remained in the hyperthermic condition for the desired period of time, the blanket is removed to allow cooling by evaporation and the restoration of normal temperature regulation. Should the patient require additional cooling to terminate the hyperthermic condition, this may be achieved by a cooling blanket or an alcohol sponge bath.

A typical test of apparatus 10, utilized a 70 kg (154 lb) pig as an animal subject. Such an animal subject resembles a human in body weight, fat distribution and in cardiac, liver and respiratory physiology. It, however, does not perspire. The animal, appropriately instrumented, was placed in apparatus 10 and heating cable 54 energized. The internal or core temperature of the animal, measured rectally, was raised to 41.8°C in about 80 minutes. Skin temperature rose to 42.5°C. Air temperature near the wall did not exceed 65°C (149°F) while adjacent to the animal, the temperature was 46°C (114°F). The pig was then removed from apparatus 10 and hyperthermic conditions maintained for two additional hours at the end of which the internal temperature was 41.6°C. The experiment was then terminated by a liberal ethanol bath. In about 90 minutes internal temperature fell to 38°C (100°F).

Tests of the above described type suggest the suitability of the present invention for use with humans.

50 CLAIMS

1. Apparatus for heating live mammalian subjects to obtain a desired increase in core temperature comprising:
a wall member defining a confined space suitable for receiving at least a selected portion of the subject, said wall member being formed of a material capable of radiating heat; means for positioning the subject portion in the space defined by said wall member;
electric heating means mounted on the exterior of said wall member generating a heat input to the wall member for providing sufficient radiant heat from the wall member to the subject portion to increase the core temperature of the subject by a physiologically signifi-

cant amount in a desired period of time, said wall member and heating means providing such radiant heat at a density low enough to minimize the possibility of superficial tissue damage to the subject; and

circuitry means connectable to a source of electric power for energizing said electric heating means.

2. The apparatus according to Claim 1 wherein said apparatus is further defined as one for obtaining core temperature increases to hyperthermic conditions in the subject, and said electric heating means is further defined as providing a heat input to the wall member sufficient to attain hyperthermic conditions in the subject.

3. The apparatus according to Claim 1 or 2 wherein said electric heating means is further defined as generating a heat input sufficient to raise the core temperature of the subject at least 4°C within a period of 120 min.

4. The apparatus according to Claim 3 wherein said electric heating means is further defined as generating a heat input sufficient to raise the core temperature of the subject 4° to 5°C in a period of 60 to 120 min.

5. The apparatus according to any preceding Claim wherein said electric heating means is further defined as mounted on the exterior of said wall member for providing uniform radiant heat from said wall member.

6. The apparatus according to any preceding Claim wherein said wall member is formed of a cupreous material.

7. The apparatus according to Claim 5 wherein said electric heating means is applied in a generally uniform manner to said wall member.

8. The apparatus according to any preceding Claim wherein said electric heating means comprises an electric heating cable applied in a generally uniform pattern to at least a selected portion of said wall member.

9. The apparatus according to Claim 7 wherein said electric heating means comprises an electric heating cable applied in a uniform pattern to a cylindrical portion of said wall member.

10. The apparatus according to Claim 8 wherein said electric heating cable comprises a plurality of cable segments electrically connected in parallel.

11. The apparatus according to Claim 9 wherein said electric heating cable comprises a plurality of cable segments electrically connected in parallel.

12. The apparatus according to any preceding Claim wherein said electric heating means provides a heat input selected in accordance with the weight of the subject.

13. The apparatus according to Claim 12 wherein said electric heating means comprises an electric heating cable having a power rating of approximately 1000 watts.

14. The apparatus according to any pre-

ceding Claim including insulation means on the exterior of said wall member and electric heating means.

15. The apparatus according to any of Claims 1 to 14 wherein said electric circuit means includes control means responsive to the temperature in said space for establishing that temperature at a desired level.
16. The apparatus according to Claim 15 wherein said electric circuit means includes further control means responsive to the temperature in said space for establishing the maximum temperature in said space.
17. The apparatus according to any of Claims 1 to 14 wherein said electric circuit means includes control means responsive to the temperature in said space for establishing the maximum temperature in said space.
18. The apparatus according to any of Claims 1 to 14 wherein said electric circuit means includes control means responsive to the temperature of said wall member for establishing the maximum temperature of said wall member.
19. The apparatus according to Claim 15 or 17 wherein said electric circuit means includes additional control means responsive to the temperature of said wall member for establishing the maximum temperature of said wall member.
20. The apparatus according to Claim 16 wherein said electric circuit means includes additional control means responsive to the temperature of said wall member for establishing the maximum temperature of said wall member.
21. The apparatus according to any preceding Claim wherein said electric circuit means includes means for establishing the period of energization of said electric heating means.
22. The apparatus according to any preceding Claim wherein said wall member is formed to define a cavity for receiving at least a portion of the subject.
23. The apparatus according to Claim 22 wherein the subject has a body and wherein said wall member is formed to define a cavity suitable for receiving the body of the subject.
24. The apparatus according to Claim 22 or 23 wherein said wall member has a generally cylindrical wall closed at one end and having openable closure means at the other end through which the subject may be received in the cavity and the cavity thereafter sealed.
25. The apparatus according to Claim 24 wherein the subject has a body and a head-connected to the body by a neck and wherein the cavity receives the body of the subject with the head extending from the cavity and wherein said closure means extends around the neck of the patient to seal the cavity.
26. The apparatus according to Claim 25 wherein said closure means includes a pair of

doors positioned across said other end of said cavity and having abutting edges located generally centrally of said wall member and wherein said doors are operable along said abutting edges.

27. The apparatus according to Claim 25 or 26 wherein said positioning means comprises a stretcher for receiving the head and body of the subject, said stretcher having means extending from said cavity by which the subject may be inserted and removed from said cavity.

28. The apparatus according to Claim 27 wherein said stretcher forms a portion of said closure means.

29. The apparatus according to Claim 1 and substantially as hereinbefore described with reference to the accompanying drawings.

Printed for Her Majesty's Stationary Office
by Burgess & Son (Abingdon) Ltd.—1983.
Published at The Patent Office, 25 Southampton Buildings,
London, WC2A 1AY, from which copies may be obtained.

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

☐ BLACK BORDERS

☒ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES

☐ FADED TEXT OR DRAWING

☒ BLURRED OR ILLEGIBLE TEXT OR DRAWING

☐ SKEWED/SLANTED IMAGES

☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS

☐ GRAY SCALE DOCUMENTS

☐ LINES OR MARKS ON ORIGINAL DOCUMENT

☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY

☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.